

**REMARKS****Summary of the Amendments**

By the foregoing amendment, claim 1 has been amended, whereby claims 1 and 3-7 will remain pending. Of the pending claims, claim 1 is independent.

The amendment made herein is being made without expressing agreement and/or acquiescence with the rejections of record, and is merely being made in an attempt to advance the present application to allowance. In particular, this amendment is made in accordance with an agreement reached with the Examiners during a telephone interview, as will be discussed below as well as to clarify claim language that the *Perilla frutescen var. crispa* polyphenols and the glycolic acid are present as a combination of active ingredients in an amount effective to achieve dissolving of dental calculus

Reconsideration of the rejections of record with allowance of the application is respectfully requested.

**Discussion of Telephone Interview**

Applicants express appreciation for the courtesies extended by Supervisory Patent Examiner Frederick Krass and Examiner Lezah W Roberts during a March 5, 2009 telephone interview to Applicants' representative Arnold Turk.

During the interview, the 35 U.S.C. 112 rejections were discussed with arguments being presented by Applicants' representative pointing to Applicants' specification for a discussion of the claimed subject matter. After discussing the

specification and the Examples therein, claim language was discussed, and the Examiners indicated that the amendment of claim 1 as presented herein should overcome the 35 U.S.C. 112 rejections.

Regarding the art-based rejection, the Examiners indicated that it will be necessary to show representative examples having unexpected results in order to convince them that unexpected results are shown for the claimed subject matter. The Examiners indicated that it will be necessary to establish that representative examples are shown of unexpected results for a sufficient range of each of the components so that the Examiners will consider the showings to be statistically significant to establish unexpected results.

#### **Information Disclosure Statement**

Applicants express appreciation for the Examiner's consideration of the information cited by Applicants, including the information whose consideration was confirmed in the Advisory Action mailed February 27, 2008 which includes a copy of an initialed Form PTO-1449.

#### **Response To Rejection Under 35 U.S.C. 112, First Paragraph**

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in that the rejection alleges that the specification does not disclose specific useful polyphenols.

In response and as noted above, the Examiners at the above-mentioned telephone interview suggested amendment of claim 1 with the indication that this

ground of rejection will be withdrawn. Accordingly, withdrawal of the rejection is respectfully requested.

In particular, the Examiners' attention is once again directed to Applicants' disclosure as originally filed which provides written description support of useful polyphenols. For example, attention is directed to page 5, beginning at line 14 regarding types of polyphenols, including *Perilla frutescen var. crispa* polyphenols rich in rosmarinic acid. Additionally, *Perilla frutescen var. crispa* polyphenols are disclosed as being sold as food improvers by Meiji Seika Kaisha, Ltd. and the examples use a 5% aqueous solution. The material as sold includes the polyphenols, and therefore it is submitted that the disclosure complies with the written description requirement.

Accordingly, this ground of rejection should be withdrawn.

#### **Response To Rejection Under 35 U.S.C. 112, Second Paragraph**

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

In response, during the above-noted interview, the Examiners agreed that the rejection would be withdrawn upon submission of the present amendment to claim 1. Accordingly, withdrawal of this ground of rejection is respectfully requested.

**Response To Art-Based Rejections**

The following rejections are set forth in the Office Action:

(a) Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136).

(b) Claims 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136), as applied to claims 1, 4 and 5, and further in view of Zhu (WO 01/17494) and Tagashira et al. (JP409295944).

Applicants once again submit that a *prima facie* cases of obviousness has not been established by any of the rejections of record. However, even if for the sake of argument a *prima facie* case of obviousness has been established in any of the rejections, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

The Examiner is reminded that 0a Declaration Under 37 C.F.R. 1.132 has been submitted on January 8, 2008, which shows the unexpected advantages associated with the recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid.

The Declaration establishes that as compared to examples using polyphenol or glycolic acid, i.e., Examples 3 and 18 of Applicants' originally filed application, respectively, an example using a combination of polyphenol and glycolic acid achieves unexpected advantages.

In particular, in Example 3 wherein *Perilla frutesen var. crispa* polyphenol was used in the absence of inclusion of additional active ingredient, 50% weight of the dental calculus was dissolved after 105 minutes, and in Example 18 wherein glycolic acid was used in the absence of inclusion of additional active ingredient, 44% weight of the dental calculus was dissolved after 9 minutes. In contrast, Applicants note that when polyphenol and glycolic acid were utilized in combination, there is obtained a more rapid dissolving of the dental calculus, i.e., 50% weight of the dental calculus was dissolved after 6 minutes.

The Office Action agrees that the relative showings in the Declaration appear to be adequate to establish unexpected results; however, the Office Action contends that the claims are not commensurate in scope with the compositions of the Declaration insofar as the claims read on any polyphenol from *Perilla frutesen var. crispa* and the Declaration discloses specific extract. In particular, the Office Action states:

As stated above there appears to be unexpected results yet the claims are not commensurate in scope with the unexpected results. The claims read on *Perilla frutesen var. crispa* that comprises polyphenols in water and not an aqueous extract of *Perilla frutesen var. crispa* comprising polyphenols as in the case of the Declaration. Furthermore, the claims are unclear insofar as it is not certain what is meant by “an aqueous solution of *Perilla frutesen var. crispa* including polyphenol”. It is difficult to ascertain whether this refers to a solution comprising *Perilla frutesen var. crispa* that naturally contains a polyphenol or if the claims refers to specific polyphenol that is obtained from *Perilla frutesen var. crispa*. If the latter is the case, Applicant has not disclosed any characteristics of the polyphenol or how it is isolated from *Perilla frutesen var. crispa*. Therefore one of skill in the art would not be able to ascertain which polyphenol of *Perilla frutesen var. crispa* is suitable for the instant method. In regards to glycolic acid, the claims only recite an amount in regards to *Perilla frutesen var. crispa* and not glycolic acid. The claims encompass any amount of glycolic acid. Therefore the instant claims are not

commensurate in scope with the Declaration and the rejection is maintained.

In response, Applicants submit that independent claim 1 as amended addresses the Examiner's concerns regarding the claimed subject matter. In particular, independent 1 is directed to an agent for dissolving dental calculus, which comprises an aqueous solution comprising *Perilla frutescen var. crispa* polyphenols and glycolic acid, the *Perilla frutescen var. crispa* polyphenols and the glycolic acid being present as a combination of active ingredients in an amount effective to achieve dissolving of dental calculus.

Thus, Applicants' independent claim 1 includes that the aqueous solution comprises *Perilla frutescen var. crispa* polyphenols. Moreover, independent claim 1 includes that the *Perilla frutescen var. crispa* polyphenols and the glycolic acid are present as a combination of active ingredients in an amount effective to achieve dissolving of dental calculus. Accordingly, Applicants' claimed subject matter is commensurate in scope with the unexpected showings in the Declaration relating to a combination of *Perilla frutescen var. crispa* polyphenols and glycolic acid, and Applicants respectfully request for withdrawal of the rejections of record.

While Applicants submit that the showing of unexpected results overcomes any *prima facie* case of obviousness, Applicants submit that a *prima facie* case of obviousness has not been established. In this regard, Applicants once again submit that the obviousness rejection based upon Melman in view of Oriza is without appropriate basis and does not establish a *prima facie* case of

obviousness. Moreover, Applicants submit that even if for the sake of argument a *prima facie* case of obviousness is considered to be established, Applicants' showing of unexpected results, as note above, overcomes any *prima facie* case of obviousness.

In this ground of rejection, the Examiner is contending that it would have been obvious to one of ordinary skill in the art to have used polyphenol extracted from *Perilla frutescens* as an antibacterial agent in the compositions of the primary reference motivated by the desire to add to the antibacterial function of the acid, as disclosed by the secondary reference.

In response, Applicants once again note that Melman's preferred active ingredient is acetic acid. Melman does disclose glycolic acid in a lengthy list of acids in paragraph [0017]; however, there does not appear to be any disclosure in Melman of glycolic acid being used in an example.

Oriza discloses oral compositions containing an extract of seeds or leaves of *Perilla frutescens crispa* or *Perilla ocimoides*.

Even if for the sake of argument one having ordinary skill in the art would have combined the disclosures of Melman and Oriza, there is no teaching or suggestion in the disclosures to have combined *Frutescens crispa* or *Perilla ocimoides* with glycolic acid, especially when Melman does not even appear to disclose an exemplary use of glycolic acid which is merely listed in his lengthy list of possible acids other than his preferred acetic acid.

Accordingly, a *prima facie* case of obviousness has not been established. However, even if for the sake of argument a *prima facie* case of obviousness has

been established, the above-noted unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

Still further, the obviousness rejection of claims 3, 6 and 7 is based upon the conclusion that:

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have added an enzyme or additional polyphenol to the compositions of the combined teachings of Melman and Oriza motivated by the desire to add the compound for its desired function, such as inhibiting adhesion of glucan and microorganisms of decayed tooth to the surface of a tooth and for its anti-calculus function, as disclosed by Zhu and Tagashira.

Applicants submit that whether or not one having ordinary skill in the art would have incorporated the disclosures of Zhu and Tagashira with that of Melman and Oriza, which Applicants submit would require improper hindsight, any combination of Melman, Oriza, Zhu and Tagashira would not have arrived at Applicants' claimed subject matter at least for the reasons set forth above with respect to independent claim 1. Moreover, Applicants' showing of unexpected results for *Perilla frutescen var. crispa* polyphenols and glycolic acid being present as a combination of active ingredients in an amount effective to achieve dissolving of dental calculus further establishes patentability of the claimed subject matter.

Accordingly, withdrawal of the rejections of record with the mailing of the Notices of Allowance and Allowability is respectfully requested.



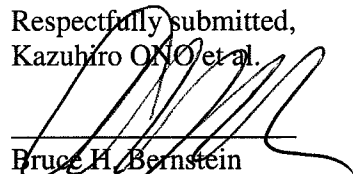
**CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
Kazuhiro ONO et al.

  
\_\_\_\_\_  
Bruce H. Bernstein  
Reg. No. 29,027

April 30, 2009  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

Reg. No. 33094  
Arnold Turk

Arnold Turk  
Reg. No. 33094